

## **REMARKS**

### **1. Application Data Sheet**

An Application Data Sheet is being submitted herewith, which includes the complete priority data for this application. As the priority data was contained in the Patent Cooperation Treaty (PCT) patent application of which the present patent application is the National Phase, no new matter has been added.

### **2. Drawings**

As requested by the Examiner, all pages after FIG. 9 have been deleted as not being drawings (they are Sequence Listings), and replacement sheets, properly labeled, are attached hereto. The lengthy captions for the figures have been deleted and incorporated into the new "Brief Description of the Drawings" section. No new matter has been added.

### **3. Specification.**

The Title has been amended as suggested by the Examiner. No new matter has been added.

A "Brief Description of the Drawings" section has been added as suggested by the Examiner. The content for this section was taken from the original captions of the figures. No new matter has been added.

One paragraph on pages 36-37 has been amended to refer to Sequence IDs 3 and 4. No new matter has been added.

### **4. Sequence Listing.**

The Sequence Listing has been replaced with the listing attached to this Response. This replacement Sequence Listing includes Seq IDs 3 and 4, which are in the original Specification on pages 36-37. No new matter has been added.

## **5. Claims Amendments.**

Claims 2, 3, and 5-21 have been amended to address the Examiner's objections and 35 USC 112 rejections in paragraphs 9 and 10, respectively, of the Office Action. No new matter has been added.

New Claims 31-33 claim a preferred embodiment of the invention, so as to more clearly define the matter for which protection is sought. These claims are derived from the application as filed, and recite a product specific for the vaccination of vertebrates - and not a product which is "destined" or "suitable for". Expressions such as "parts of pollen grains", "fragments thereof" were not included. New claim 31 does not refer to any process. In this regard, please note that the promoter sequence of the glycine-rich protein gene *AtGRP17* of *A. thaliana* is actually present in the pollen grains of the invention, as well as the heterologous polypeptide expressed under its control. Accordingly, both are now referred to as ingredients of the product. The new claim wording does not extend beyond the content of the application as filed. No new matter has been added.

## **6. 35 USC 102(b) Rejection**

Applicant initially submits that Claims 1-3 and 5-21 as amended are not anticipated by WO 99/49063 to Robert (Robert '063).

Additionally, new Claims 31-33 have been crafted to even further differentiate the invention from Robert '063. Robert '063 discloses different means for expressing heterologous polypeptides than those described in the present application. Also, Robert '063 only recites that heterologous polypeptides *could be* expressed in the corresponding cells, but no single example supports the use of pollen grains as direct vaccination means. Notwithstanding, new Claims 31-33 are further novel over Robert '063 as Robert '063 does not mention or suggest the use of the promoter sequence of the glycine-rich protein gene *AtGRP17* of *A. thaliana*. Additionally, Robert '063 does not mention or suggest the use of the promoter sequence of the glycine-rich protein gene *AtGRP17* of *A. thaliana* in combination with the corresponding coding region in a translational fusion with the polypeptide of interest. Please also note in this regard that:

- (i) in Robert '063, the disclosed promoters and/or their coding regions are Sta 41-2 or Sta 41-9, Sta 44, SLGws, or MOO 11, which are different from that of the present invention (AtGRP17); and
- (ii) AtGRP17 gene product (which is used in translational fusion in the product of the invention) has 49 kDa and is the most abundant protein of the pollen grain surface, corresponding to 21% of the total protein content of the surface pollen grain (please refer to Mayfield & Preuss, 2000, attached hereto). AtGR17 gene product is also known to enhance the stability of pollen grains and to interfere with its hydration process.

Accordingly, the use of the strategy of the present invention is an alternative to that disclosed in Robert '063. The present invention clearly does provide benefits over Robert '063; the substantial test results provided in the present application as filed are robust proof of concept of the use of whole pollen grains under several regimes for obtaining a consistent, statistically significant, and highly unexpected protection-like response, as revealed by the cellular and molecular responses detected and disclosed in the application as filed.

As such, Applicant submits that the claims, including new Claims 31-33, are not anticipated by Robert '063, and requests that the Examiner withdraw this grounds for rejection.

**CONCLUSION**

Applicant submits that the application and claims are in condition for allowance and respectfully requests such action. If the examiner has any questions that can be answered by telephone, please contact the patent attorney of record at the **NEW** address and telephone number listed below.

Respectfully submitted,  
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